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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/787,323 | 03/16/2001 | Daniel Keith Burns | PU3562USW | 9629 |

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EXAMINER

JOHANNSEN, DIANA B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1634

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,323

Applicant(s)

BURNS ET AL.

Examiner

Diana B. Johannsen

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 14 is/are rejected.
- 7) ☒ Claim(s) 7, 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 1/2; 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Notice to Comply*.

FINAL REJECTION

1. This action is in response to paper no. 7, filed June 5, 2002, and paper no. 12, filed November 26, 2002. Claims 1-11 have been amended, claims 12-13 have been canceled, and claim 14 has been added. Claims 1-11 and 14 are now pending and under consideration. The amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statements

3. The information disclosure statement filed November 9, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Specifically, legible copies of document numbers 3-9 have not been provided. Regarding document numbers 3-8, copies of the documents have been provided; however, the documents have been photocopied in such a way that portions of each of the documents are not legible. Accordingly, the documents have been placed in the application file, but the information referred to therein has not been considered.

4. Regarding the information disclosure statement filed March 16, 2001, it appears that a signed copy of the Form PTO-1449 provided by applicant was not provided with the previous Office action. Accordingly, that copy is enclosed herewith.

Compliance with Sequence Rules

5. The paper and computer readable forms of the Sequence Listing filed November 26, 2002, have been entered. It is noted that Applicant has indicated that the sequence in Figure 3B is "for illustrative purposes only" and has requested that requirements for sequence compliance be waived with respect to this sequence. However, the examiner cannot waive this requirement, which is dictated by 37 CFR § 1.821-1.825. Applicant is referred to *MPEP* 2422.02, which states that "...when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings." Accordingly, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures, and appropriate corrections for compliance are required.

6. It is noted that the sequence depicted in Figure 3B is at least partly illegible (see also the objection to this Figure on the enclosed Form PTO-948). As the sequence in Figure 3B was not legibly disclosed in the instant application or in any of the applications to which the instant application claims priority, it appears that the filing of a

substitute Figure and an addition of the Figure 3B sequence to the specification/sequence listing would introduce new matter. Accordingly, as the sequence in Figure 3B is merely illustrative, it is suggested that applicant either provide a substitute Figure 3B that excludes the recitation of a nucleotide sequence, or cancel the Figure and any reference to it in the specification.

Claim Objections

**THE FOLLOWING ARE NEW GROUNDS OF OBJECTION NECESSITATED BY
APPLICANTS AMENDMENTS TO THE CLAIMS:**

7. Claims 7 and 9 are objected to because of the following informalities. In lines 2-3 of claim 7, the claim recites "the an electrophoresis sequencing device" whereas it should recite, e.g., "the electrophoresis sequencing device." Claim 9 does not end in a period. Appropriate correction is required.

Claim Rejections - 35 USC § 112

**THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY
APPLICANTS AMENDMENTS TO THE CLAIMS:**

8. Claims 1-11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 are indefinite because it is unclear as to whether the claims are intended to be drawn to a method "of identifying a nucleotide sequence of a nucleic acid," as recited in the preamble of claim 1, or to a method of "performing gel or capillary electrophoresis" on multiple sequencing reaction products, as recited in the

final process step. The claims do not make clear whether the performance of electrophoresis is sufficient to meet the requirements of the claims, or whether the claims actually require determining or identifying the nucleotide sequence of one or both of the sequencing reaction products. Clarification is required.

Claims 1-5 are indefinite over the recitation of the limitation "the first short sequencing reaction product" in claim 1. There is insufficient antecedent basis for this limitation in the claims.

Claims 1-5 are indefinite over the recitation of the limitation "the second short sequencing reaction" in claim 1. While claim 1 previously refers to a "second short sequencing reaction product" and a "second sequencing reaction product," the claim does not previously recite a "second short sequencing reaction" (as opposed to a "second short sequencing reaction product"). This rejection could be overcome by amending the claim to recite "the second short sequencing reaction product."

Claims 1-5 are indefinite over the recitation of the phrase "performing gel or capillary electrophoresis on the first short sequencing reaction product and on the second short sequencing reaction" in claim 1. Claim 1 previously recites steps of loading first and second sequencing reaction products into lanes of a "sequencing gel." It is unclear as how the step of "performing gel or capillary electrophoresis" is intended to further limit the claimed method. For example, is this recitation intended to indicate that electrophoresis is to be performed on the "sequencing gel" into which samples were previously loaded, or is this recitation intended to indicate that separate steps of either "gel electrophoresis" or "capillary electrophoresis" is to be performed on the same

samples? Clarification is required with respect to how the "loading" and "performing...electrophoresis" steps of the claimed method relate to one another.

Claims 6-11 are indefinite because it is unclear as to whether the claims are intended to be drawn to a method "of determining the nucleotide sequence of a portion of a nucleic acid," as recited in the preamble of claim 6, or to a method of "performing electrophoresis analysis" on a sequencing reaction product, as recited in the final process step. The claims do not make clear whether the performance of electrophoresis is sufficient to meet the requirements of the claims, or whether the claims actually require determining or identifying the nucleotide sequence of a reaction product. Clarification is required.

Claims 10-11 are indefinite over the recitation of the limitation "the electrophoresis," because there is insufficient antecedent basis for this limitation in the claims.

Claim 14 is indefinite because it is unclear as to whether the claim is intended to be drawn to a method "of determining the nucleotide sequence of a portion of a nucleic acid," as recited in the preamble of claim 14, or to a method of "performing mass spectrophotometry" on a sequencing reaction product, as recited in the final process step. The claim does not make clear whether the performance of mass spectrophotometry is sufficient to meet the requirements of the claim, or whether the claim actually requires determining or identifying the nucleotide sequence of a reaction product. Clarification is required.

Claim 14 is indefinite over the recitation of the limitation "the amplified fragment" in step d). There is insufficient antecedent basis for this limitation in the claim.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
February 20, 2003

Carla J. Myers
CARLA J. MYERS
PRIMARY EXAMINER